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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/808,832

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EXAMINER

PHONGSVIRAJATI, POONSIN

ART UNIT

PAPER NUMBER

4176

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/808,832	Applicant(s) KONDO, SEIJI	
	Examiner SIND PHONGSVIRAJATI	Art Unit 4176	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040325</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Hommachi (JPO 2001-256305).

3. As to **Claim 1**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, and a single or a plurality of research institutions distribute the medical information with one another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- a step of transmitting the medical information obtained by use of apparatuses and/or consumables such as reagent associated consumables to obtain the medical information from a patient or a specimen to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22, the Examiner takes the position it is inherent that the individuals [referred in item 17 from Fig.1] must sample their genome at a medical care/test institution);

- a step of searching a database by the use of the medical information received from the medical care/test institution to return a search result to the medical care/test institution, and changing the medical information received from the medical care/test institution into a predetermined format to store clinical data in the database in the information management institution (Hommachi, paragraph 21);
 - a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
 - a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21), wherein the apparatuses and/or the consumables such as the reagent associated consumables to obtain the medical information are supplied to the medical care/test institution from the information management institution at a charge or free of charge (Hommachi, paragraphs 34-36).
4. As to **Claim 2**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, a single or a plurality of research institutions, and a single or a plurality of manufacturing/selling institutions of apparatuses and/or consumables such as a reagent associated consumable distribute the medical information with one

another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- a step of transmitting the medical information obtained by use of apparatuses and/or consumables such as reagent associated consumables to obtain the medical information from a patient or a specimen to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22, the Examiner takes the position it is inherent that the individuals [referred in item 17 from Fig.1] must sample their genome at a medical care/test institution);
- a step of searching a database by the use of the medical information received from the medical care/test institution to return a search result to the medical care/test institution, and changing the medical information received from the medical care/test institution into a predetermined format to store clinical data in the database in the information management institution (Hommachi, paragraph 21);
- a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21), wherein the

apparatuses and/or the consumables such as the reagent associated consumables to obtain the medical information are supplied to the medical care/test institution from the information management institution at a charge or free of charge (Hommachi, paragraphs 34-36), and

- a rebate is supplied to the manufacturing/selling institutions of the apparatuses and/or the consumables such as the reagent associated consumables from the information management institution (Hommachi, paragraphs 33, and 37).

5. As to **Claim 3**, Hommachi teaches a distribution method of medical information, in which a single or a plurality of medical care/test institutions, an information management institution, and a single or a plurality of research institutions distribute the medical information with one another, the distribution method of the medical information (Hommachi, Abstract, Fig.1), comprising:

- a step of sending a specimen to the information management institution from the medical care/test institution (Hommachi, paragraphs 21-22);
- a step of obtaining the medical information with respect to the sent specimen in the information management institution (Hommachi, paragraph 21);
- a step of searching a database by use of the medical information to return a search result to the medical care/test institution, and changing the obtained medical information into a predetermined format to store clinical data in the database (Hommachi, paragraphs 21-22);

- a step of transmitting an inquiry for the clinical data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of searching the database based on the inquiry received from the research institution to return the search result to the research institution from the information management institution (Hommachi, paragraph 21).

6. As to **Claim 4**, Hommachi teaches the distribution method of the medical information according to claim 1, further comprising:

- a step of transmitting specific medicine data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

7. As to **Claim 5**, Hommachi teaches the distribution method of the medical information according to claim 2, further comprising:

- a step of transmitting specific medicine data to the information management institution from-the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

8. As to **Claim 6**, Hommachi teaches the distribution method of the medical information according to claim 3, further comprising:

- a step of transmitting specific medicine data to the information management institution from the research institution (Hommachi, paragraphs 21 and 27); and
- a step of updating the database by the received medicine data in the information management institution (Hommachi, paragraphs 16-21).

9. As to **Claim 7**, Hommachi teaches the distribution method of the medical information according to claim 1, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

10. As to **Claim 8**, Hommachi teaches the distribution method of the medical information according to claim 2, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

11. As to **Claim 9**, Hommachi teaches the distribution method of the medical information according to claim 3, wherein a fixed global IP address is attached to the apparatus to obtain the medical information (Hommachi, paragraphs 25 and 35).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hommachi (JPO 2001-256305).

14. As to **Claims 10-12**, Hommachi does not specifically teach the distribution method of the medical information, further comprising: a step of subjecting the medical information to an interpolation preventive measure and encryption. But, the Examiner takes official notice that it would have been self-evident/inherent to encrypt an individual's data and clinical history to allow access to only authorize personnel in order to ensure a patient's privacy.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention, to have modified the system of Hommachi to include preventive measures such as encryption, since in doing so would protect an individual's privacy and so doing could be performed readily and easily by any person of ordinary skill in the art, with neither undue experimentation, nor risk of unexpected results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 4176
21 July 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 4176